

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
)	C.A. No. 21-1015 (JLH)
v.)	
)	DEMAND FOR JURY TRIAL
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
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SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

**PLAINTIFF'S OMNIBUS REPLY BRIEF IN SUPPORT OF ITS *DAUBERT* MOTIONS
TO EXCLUDE TESTIMONY AND OPINIONS OF STEVEN F. DOWDY, PH.D**

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
Zachary Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
110 N. Wacker Drive, Suite 2800
Chicago, IL 60601
Telephone: 312.324.1000 | Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

Amy M. Dudash (DE Bar No. 5741)
MORGAN, LEWIS & BOCKIUS LLP
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Telephone: 302.574.3000 | Fax: 302.574.3001
amy.dudash@morganlewis.com

Alison P. Patitucci (admitted *pro hac vice*)
2222 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000 | Fax: 215.963.5001
alison.patitucci@morganlewis.com

*Attorneys for Plaintiff/Counterclaim Defendant
Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: January 26, 2024

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I. THE COURT SHOULD EXCLUDE DR. DOWDY’S OPINIONS (*DAUBERT* MOTION # 1)

Dr. Dowdy’s New Construction of “Antisense.” Sarepta disingenuously represents that “it was not until service of Dr. Hastings’ Opening Expert Report on September 8, 2023, that it became clear that NS” would “contend[] that outside of the ‘base sequence,’ the ASOs of the Wilton Patents can include *up to 19* random nucleotides that are *not complementary* to the target region.” D.I. 467 at 4 (emphasis original). Sarepta’s expert, Dr. Cy Stein, however, illustrated this *very scenario* during claim construction:

Under NS’s construction, the amount of non-complementary bases that a claimed antisense oligonucleotide could have is substantial. For example, an antisense oligonucleotide of 31 bases could have 12 bases derived from SEQ ID NO: 195 (which would be 100% complementary) and 19 bases that are completely unrelated to the dystrophin gene (*which would have 0% complementar[ity]*).

D.I. 171-53, Stein Reply Decl. ¶ 19. Sarepta acknowledged this consequence of NS’s construction both in briefing and oral argument. D.I. 166 at 32-33; Ex. 61, Claim Constr. Hr’g at 22:16-21.

The Court resolved this dispute in NS’s favor. It found that “the plain language only requires that the claimed antisense oligonucleotide includes at least ‘a base sequence,’ while allowing for additional elements, *e.g.*, additional bases . . . including non-complementary base sequences.” D.I. 248 at 8-9. At no point did Sarepta indicate, much less advise the Court, that adopting NS’s construction would “disregard the claim term ‘antisense’ oligonucleotide altogether” as it now claims. D.I. 467 at 4. But more importantly, by rejecting Sarepta’s argument that “NS wrongly eliminates the requirement for 100% complementarity” across the entire “antisense oligonucleotide,” (D.I. 248 at 9), the Court held that only a “part of the antisense oligonucleotide” (the “base sequence”) needed to be complementary, such that—as both parties’ then-agreed—“the ASOs of the Wilton Patents can include *up to 19* random nucleotides that are *not complementary* to the target region,” (D.I. 467 at 4 (emphasis in original)).

That should end this matter. Sarepta is not entitled to belatedly re-argue that there is any complementarity requirement “outside of the ‘base sequence’” when the Court ruled that none exists. *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010) (“[r]estating a previously settled argument does not create” an *O2 Micro* dispute); *Align Tech., Inc. v. 3Shape A/S*, No. 17-1646, 2020 WL 4926164, at *7-8 (D. Del. Aug. 14, 2020) (Stark, J.) (striking opinions that were “contrary to the Court’s construction” or “improperly narrow[ed]” its construction).

Even if the Court adopted Dr. Dowdy’s new construction of “antisense” as requiring “high complementarity,” it should still exclude Dr. Dowdy’s genus calculations in paragraphs 57-58 and Exhibit C of his Rebuttal Report. *See* D.I. 421 at 3, n. 2. These calculations “allow[] for a mismatch or an insertion versus the exon 53 pre-mRNA” *Id.* ¶ 57-58. But Dr. Dowdy later confirmed [REDACTED] Ex. 60, (Dowdy Dep.) at 16:4-7 ([REDACTED]); *id.* at 24:18-23, 36:3-17 ([REDACTED]). Dr. Dowdy [REDACTED].¹ The Court should therefore exclude Dr. Dowdy genus calculations as materially incomplete and misleading.

Dr. Dowdy’s Inequitable Conduct Opinions. Sarepta spends much of its response arguing that Dr. Dowdy should be permitted to testify “on the technical matters that are assessed from the perspective of a POSA.” D. I. 467 at 7. As NS made clear in its Opening Brief, “NS is not seeking to preclude Dr. Dowdy from offering opinions about technical aspects of the claimed invention, the prior art, and data NS allegedly ‘withheld’ from the Patent Office, and how, in his opinion, this

¹ As Dr. Hastings explains, allowing for two mismatches greatly expands the number of possible PMOs falling within the scope of the UWA Patent claims. D.I. 427-7, Hastings Reply ¶ 19.

affects the validity of the NS Patents.” D.I. 421 at 5, n.4. And Sarepta does not dispute NS’s position that the Court should preclude Dr. Dowdy from using legal terminology characterizing information as “material” or that NS “withheld” and engaged in a “pattern of withholding” certain information from patent offices. Thus, paragraphs with those legal descriptors should be struck.

Dr. Dowdy’s Reliance on the IPRs.² Sarepta cites two decisions denying motions to exclude evidence of IPR proceedings, both of which are distinguishable because they involved IPR institution *denials*. D.I. 467 at 10. Moreover, in *WhereverTV*, the Court explained that the IPR proceedings “are relevant to impeach Comcast’s expert, Dr. Terveen, who has endorsed prior art combinations that the PTAB rejected.” *WhereverTV, Inc. v. Comcast Cable Commc’ns, LLC*, No. 18-cv-529, 2023 WL 2664200, at *7 (M.D. Fla. Mar. 28, 2023). Here, in contrast, NS did not offer any expert opinions in the IPRs and Sarepta’s IPR expert, Dr. David R. Corey, is not a testifying expert in this litigation.

II. THE COURT SHOULD EXCLUDE MR. HIRSHFELD’S OPINIONS (DAUBERT MOTION #2)

Sarepta contends that the paragraphs challenged by NS (D.I. 427-8 at ¶¶ 22-31, 69-75, 86-100 and D.I. 428-9 at ¶¶ 12-14) were merely responding to Dr. Kamholz’s erroneous application of written description and enablement law, and incorrect recital of inventorship law. D.I. 467 at 11-12 (citing ¶¶ 32, 35, 47-48, 61, 66-67, 72-75, and 83 of Dr. Kamholz’s Opening Report). Sarepta does not explain how Dr. Kamholz erred or was wrong in its brief, nor do the purportedly responsive paragraphs from Mr. Hirshfeld’s reports provide such an explanation or reference to Dr. Kamholz’s opinions. Paragraphs 22-31, 69-75, 86-94 and 96-100 from Mr. Hirshfeld’s

² To the extent Sarepta is correct that the parties did not meet and confer on this topic, any such failure on behalf of NS was inadvertent. Moreover, Sarepta clearly opposes the motion and Sarepta does not contend that the parties could have reached agreement had the parties met and conferred. Sarepta also does not contend that it has been prejudiced by the parties’ failure to meet and confer. Accordingly, the Court should consider NS’s motion on the merits.

Opening Report (D.I. 427-8) cannot fairly be viewed as responsive to Dr. Kamholz's opinions. They are under the heading "IV. Overview of the U.S. Patent System" and are merely a generalized recitation of law. They precede any discussion of facts specific to this case, do not offer any factual analysis, or address Dr. Kamholz's analysis. However, even if any of the challenged paragraphs were responsive to Dr. Kamholz's opinions, that does not make their recitation of the law any more permissible. Unlike Sarepta, who seeks to exclude Dr. Kamholz's opinions wholesale (D.I. 391), NS focused on truly objectionable paragraphs in Mr. Hirshfeld's reports.

For the reasons set forth in NS's opening briefs (D.I. 421, 424), NS requests the Court grant its *Daubert* motions.

Dated: January 26, 2024

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
Zachary D. Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
110 N. Wacker Drive, Suite 2800
Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

/s/Amy M. Dudash
Amy M. Dudash (DE Bar No. 5741)
1201 N. Market Street, Suite 2201
Wilmington, Delaware 19801
Telephone: 302.574.3000
Fax: 302.574.3001
amy.dudash@morganlewis.com

*Attorneys for Nippon Shinyaku Co.,
Ltd. and NS Pharma, Inc.*

Alison P. Patitucci (admitted *pro hac vice*)
1701 Market Street

Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001
alison.patitucci@morganlewis.com

CERTIFICATE OF SERVICE

The undersigned certifies that on January 26, 2024, a copy of the foregoing, which was filed under seal, was served via electronic mail on the following counsel of record:

Jack B. Blumenfeld
Megan E. Dellinger
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street, 16th Floor
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

William B. Raich
Michael J. Flibbert
John M. Williamson
Yoonhee Kim
Yoonjin Lee
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000
william.raich@finnegan.com
michael.flibbert@finnegan.com
john.williamson@finnegan.com
yoonhee.kim@finnegan.com
yoonjin.lee@finnegan.com

Charles E. Lipsey
J. Derek McCorquindale
Ryan P. O'Quinn
L. Scott Burwell
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
1875 Explorer Street, Suite 800
Reston, VA 20190-6023
(571) 203-2700
charles.lipsey@finnegan.com
derek.mccorquindale@finnegan.com
ryan.o'quinn@finnegan.com
scott.burwell@finnegan.com

Alissa K. Lipton
Eric J. Lee, Ph.D.
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210-2001
(617) 646-1600
alissa.lipton@finnegan.com
eric.lee@finnegan.com

Amanda P. Reeves
Anna M. Rathbun
Graham B. Haviland
Jesse Aaron Vella
Michael A. Morin
David P. Frazier
Rebecca L. Rabenstein
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, D.C. 20004-1359
(202) 637-2200
amanda.reeves@lw.com
anna.rathbun@lw.com
graham.haviland@lw.com
jesse.vella@lw.com
michael.morin@lw.com
david.frazier@lw.com
rebecca.rabenstein@lw.com

Ernest Yakob
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020-1300
(212) 906-1200
ernest.yakob@lw.com

/s/ Amy M. Dudash
Amy M. Dudash (DE Bar No. 5741)